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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,962	02/02/2004	Darin G. Schaeffer	10703/042	9118
7590 02/21/2008 BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204			EXAMINER ALI, SHUMAYA B	
			ART UNIT 3771	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/769,962	Applicant(s) CT SCHAEFFER ET AL.	
	Examiner SHUMAYA B. ALI	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 6-32 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

In response to the office action dated 9/7/07, Applicant has amended claims 1, 12, and 22. Claim 2 is previously cancelled. Currently claims 1 and 3-32 are pending in the instant application.

Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The indicated allowability of claims 10, 11, and 32 is withdrawn in view of the newly discovered reference(s) to Weinstein US 5,217,005 and Collins 6,799,574. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-21 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinstein US 5,217,005.

As to claim 12, Weinstein discloses an insertion device (10) comprising a tracheostomy tube (20) and a loading dilator (11), the tracheostomy tube having a longitudinal bore (interior passage of tube 20. Figure 1 shows dilator (11) is positioned along the length of the tube (20));

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the loading dilator having a larger-diameter stepped proximal portion (12,14) and a smaller diameter distal portion (diameter of 11 is smaller than diameter of 12 and 14) extending from said larger diameter proximal portion (see fig.2), said smaller diameter distal portion having a generally cylindrical profile (11a is generally cylindrical profile) and having a tapered at its distal end (11a), the smaller-diameter distal portion being sized to be insertable through the longitudinal bore of said tracheostomy tube such that said tapered distal end extends axially beyond the tapered distal tip of the tracheostomy tube (see figs.1 and 2), the tracheostomy tube having a proximal end (24 is located at the proximal end) and further comprising a stop portion (24) at said proximal end for engaging a distal portion of the larger-diameter stepped portion of the dilator to limit axial movement of the loading dilator through the tracheostomy tube (see fig.1. Axial movement of the dilator 11 is limited when extension in front of handle 14 comes in contact with flange 24). Weinstein further discloses the tube has a tapered distal end (16 and 17).

As to claim 13, Weinstein discloses wherein said stop portion comprises a collar (14) provided at said proximal end of said tracheostomy tube.

As to claim 14, Weinstein discloses wherein said stop portion (24) comprises a larger-diameter proximal end portion of the tracheostomy tube (see fig.1).

As to claim15, Weinstein discloses wherein said tapered distal end of said dilator is complementary to the tapered distal tip of the tracheostomy tube such that a generally smooth conical insertion tip is defined thereby (see figs. 1 and 2).

As to claim 16, Weinstein discloses wherein said generally smooth conical insertion tip has a profile sufficient for dilating an opening in the body of a patient for insertion of said tracheostomy tube (see figs. 3-6).

As to claim 17, Weinstein discloses wherein said larger-diameter stepped proximal portion of the dilator comprises a gripping surface (14) (see also col.3 lines 15 and 16).

As to claim 18, Weinstein discloses wherein said gripping surface is formed from one or more polymers (Teflon is a polymer, see col.3 line 23).

As to claim 19, Weinstein discloses wherein said gripping surface is formed from a member selected from the group consisting of lower durometer urethanes, thermoplastic rubbers, thermoplastic elastomer and non-thermoplastic elastomer (see Teflon in col.3 line 23).

As to claim 20, Weinstein discloses wherein said dilator larger-diameter stepped proximal portion and smaller diameter distal portion comprise integral molded components (see fig.2).

As to claim 21, Weinstein discloses said larger diameter stepped proximal portion of said dilator includes a longitudinal passageway, and a portion of said smaller diameter distal portion is securely received within said longitudinal passageway (see fig.2).

As to claim 32, Weinstein discloses wherein said loading dilator has a central lumen extending substantially therethrough (see lumen of 11 in figure 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lester US 5,928,198.

As to claim 1, Lester discloses a tracheotomy tube (fig.1, 10) comprising: a hollow tubular body having a proximal end portion (proximal end is away from the body/toward flange 15), a distal end portion (opposite end of the proximal) and a curved portion intermediate said proximal and distal end portions (fig.1 depicts a curved portion between the distal and proximal end of the tube); and a flange (15) situated at said proximal end portion, said flange being capable of selective attachment to said tubular body and removable therefrom, said flange extending radially from said proximal end portion when attached thereto (col.2 lines 18-40). Even though Lester lacks explicit teachings of selective attachment and removable of the flange as claimed, Lester's teachings of a flange that can be adjusted to place the flange at a various combination of locations along the tube render selective attachment and removable of the flange as claimed obvious. Lester discloses a flange that has a flexible plate to which two semi-circular arms are attached and hinged with one another. Lester further discloses the arms can be clamped hinged with one another to lock the flange at any location along the tube (see col.2 lines 32-38). Thus, movement of Lester's flange from a first to second locations along the tube would inherently require one of ordinary skill in the art to detach/remove the arms at the first location,

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and then reattach the arms at the second location. Furthermore, Lester's teaching of a flange with long arms at the proximal end of a tube would inherently prevent any radial extending of the tube. Therefore, it would have been obvious to one of ordinary skill in the art to derive the intended use of the flange as claimed using the flange of Lester.

As to claim 3, Lester lacks wherein said flange is attachable to said tube by a snap-fit. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to attach the flange using known attachment means including a snap fit.

Claims 4, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Montgomery US 4,269,184

As to claim 4, Lester discloses wherein said flange includes a cut-away portion (see labeled fig.1, attached below), collar (12), however, Lester lacks wherein said collar having a groove, and said groove being cooperatively sized and shaped to mate when said flange is attached to said tube, however, Montgomery teaches grooves on an endotracheal tube can serve to secure the apertures face plate 20 (flange) (see col.3 lines 17-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide grooves on the tube of Lester in order to secure the flange as taught by Montgomery.

As to claim 6, Lester discloses wherein said collar is integral with the hollow tubular body (see fig.1)

As to claim 7, Lester lacks wherein said collar includes one or more barbs for attaching the collar to said hollow tubular body. However, barb structures are disclosed, as an alternative species to the integral collar of claim 6, which is also taught by Lester, therefore would not

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require an additional structure, i.e. barbs for attachment to the tubular body. Therefore, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have an integral collar which does not require any attachment means, or barbs attaching the collar to the tubular body because Applicant has not disclosed that "one or more barbs" provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with integral attachment of the collar taught by Lester because the function of the tube when providing tracheostomy would not be affected by a specific type of attachment means on the collar.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Fauza US 6,612,305B2

As to claim 8, Lester lacks removable inner cannula insertable in said hollow tubular body. However, Fauza teaches inner cannula (fig.2, 5) which can be removed in case of severe acute obstruction of it, for example by mucous secretions, allowing for immediate establishment of air flow through the outer tube, and for easier cleaning of the inner tube (see col.3 lines 65-68, col.4 lines 1-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the tube of Lester with inner cannula as a matter of design choice because it is known in the art to have tracheostomy tube with inner and outer cannula as taught by Fauza, and furthermore, it is also known in the art that one of ordinary skill in the art would choose a tracheostomy tube with an inner and outer cannula so that the outer cannula can be placed at a fixed position with respect to patient's trachea while inner cannula can be used for guiding surgical instrument, furthermore, if the surgery required continuous rinsing

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of the tube due to mucous secretion, then it is convenient to just pull out the inner tube while keeping the outer cannula fixed in the patient, this way the surgeon does not have to repeat the steps of placing the tube in the patient every time the tube needed a rinse.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198 in view of Ranford et al. US 4,235,229

As to claim 9, Lester lacks wherein said hollow tubular body includes an inflatable cuff surrounding a part of said distal end portion, said tracheostomy tube further comprising an inflation line connecting said cuff to a source of an inflation fluid, however, Ranford teaches inflatable cuff (fig.1, 21) that can be inflated by inflation line (fig.1, 22) to provide a seal between the tracheostomy tube and the patient's trachea (see col.2 lines 60-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the tube of Lester with an inflatable cuff with an inflation line so that the cuff can be inflated and doing so would provide a seal between the tube and the patient's trachea as taught by Ranford.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198/ Ranford et al. US 4,235,229 and further in view of Collins US 6,799,574 B1.

As to claim 10, Lester lacks inflation line being selectively peelable. However, Collins teaches peelable inflation tube that allows the inflation line to be kept neatly with the tube shaft along most of the length (see col.3 lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lester in order to provide a peelable inflation line for the purposes of allowing the Inflation line to be kept neatly with the tube shaft along most of the length as taught by Collins.

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Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lester US 5,928,198/ Ranford et al. US 4,235,229, Collins US 6,799,574 B1, and further in view of Rutter US 7,140,369B2.

As to **claim 11**, Lester lacks said hollow tubular body is trimmable along a trim line. However, Rutter teaches that the trimming proximal end of the tracheal tube is known in the art for accommodating the size of both adult and child patient (see col.4 lines 5-10). It is obvious that a trim line is chosen by an operator, therefore, the line is located where the cut is made. Therefore, it would have been obvious to one of ordinary skill in the art to modify Lester in order to provide a trim line for the purposes of accommodating the tube for various size patients, i.e., adult/child, as taught by Rutter.

Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neame US 6,481,436 in view of Sudge US 6,408,850 B1.

As to **claim 22**, Neame discloses a device for precutaneous insertion into the trachea of a patient, comprising: a tracheotomy tube (1) having a longitudinal passageway (interior passage of tube 1. Figure 1 shows member 2 is positioned along the length of the passageway) there through, said tracheotomy tube having a distal end (11) portion precutaneous insertable into said trachea and a proximal end (toward 12) portion exterior to the trachea when said distal end portion is inserted; a locking assembly (34,34,35) for locking the tracheotomy tube to the dilator during insertion of said tracheotomy tube into the trachea, A dilator (2) positionable within said longitudinal passageway of said tracheostomy tube for dilating an opening in said trachea for insertion of said tracheostomy tube.

Neame however lacks a flange is selectively attached and removed form the tube after

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said distal end portion has been inserted into the trachea. However, Sudge teaches a flange (1), which is selectively attached or removed from a tube (4) by respectively engaging and disengaging arms (2 and 3) on the flange. Flange of Sudge prevents axial displacement of the tube and provide an engagement surface for a harness (5) (see fig.4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Neame in order to provide a flange for the purposes of preventing axial displacement of the tracheal tube by when the flange is engaged to the tube and allowing axial displacement of the tube by disengaging the arms on the flange as taught by Sudge.

As to claim 23, Neame discloses wherein said locking assembly comprises a securement member (3, 35) associated with the dilator, said securement member engageable with a complementary member (15) on said tracheostomy tube..

As to claim 24, Neame discloses wherein said locking assembly further comprises a stop (33) member disposed on an outer surface of said dilator, said stop member engaged with said dilator such that substantial axial movement of said stop member along said dilator is prevented when an axial force is applied to said stop member (see fig.1), said stop member positioned on said outer surface and engageable with said securement member and said complementary member for preventing excess penetration of tracheostomy tube into the trachea (see fig.1).

As to claim 25, Neame discloses wherein said stop member comprises an annular ring (33) integral with said dilator (see fig.4).

As to claim 26, Neame discloses wherein said stop member comprises an annular ring fitted on the outer surface of said dilator (see fig.1).

As to claim 27, Neame discloses wherein said complementary member comprises a collar (13) integral with said tracheostomy tube (figure 1).

As to claim 28, Neame discloses wherein said complementary member comprises a collar (13) fitted on an exterior surface of said tracheostomy tube (see fig.1).

As to claim 29, Neame lacks wherein said securement member comprises a cap member having one or more screw threads engageable with said complementary member for locking said tracheostomy tube to said dilator, however, Neame teaches snap fitted locking means as applied for claim 22. Since Applicant has not stated why a specific type of locking means are critical to the invention in terms of providing a specific function or solving a stated problem, one of ordinary skill in the art would consider Applicant's invention to perform equally well with the snap fitted locking means taught by Neame because the ability of the locking means to hold the tube in a stable position would not be affected by the type of locking means. Therefore, it would have been an obvious matter of design choice to modify Neame to obtain the invention as specified in claim 29.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ranford et al US 4,235,229 in view of Rutter US 7,140,369B2.

As to claims 30, Ranford teaches providing a tracheostomy tube comprising a hollow tubular body (11) having a longitudinal passageway therethrough, said tubular body having a distal end (toward cuff 21) portion for insertion into the trachea and a proximal end (toward 30) portion exterior to the trachea when the distal end portion is inserted, said tubular body further having a curved portion (see fig.1) intermediate said proximal portion. Tube (11) is a tracheostomy tube, thus the distal end portion is inherently inserted into a trachea. Ranford also

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teaches engaging a flange (33) which can be engaged at said proximal portion following insertion of said distal end portion. Ranford however lacks the step of trimming an excess portion of said proximal end portion of said tubular body. However, Rutter teaches that the trimming proximal end of the tracheal tube is known in the art for accommodating the size of both adult and child patient (see col.4 lines 5-10) as applied for claim 11. Weinstein teaches a flange (14),

As to claim 31, Ranford in figure 1 shows the flange is attached to a collar (30), said collar being connected to said proximal end portion.

Response to Arguments

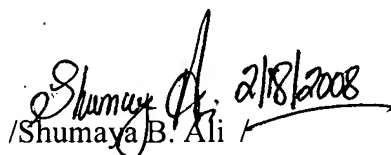
Applicant's arguments filed on 12/5/07 with respect to claim 1 have been fully considered but they are not persuasive. Applicant primarily argues that Lester does not teach selectable attachment to, and removed from, the tubular body of the tracheostomy tube (see page 6 lines 25 and 26). However, Examiner contends since the claim is not requiring a complete removal of the flange from the tube, the sliding movement of Lester's flange continues read on the amended limitation. Bolt (18) in Lester can be adjusted to remove flange to slide the flange from a first to a second position along the length of the tube.

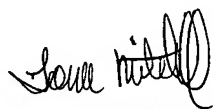
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner, Art Unit 3771


TEENA MITCHELL
PRIMARY EXAMINER
2/18/08

